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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,403	01/30/2004	Gregory Murphy	5838-03103	3788

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EXAMINER	
BITAR, NANCY	
ART UNIT	**PAPER NUMBER**
2624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,403	MURPHY ET AL.	
	Examiner	Art Unit	
	Nancy Bitar	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *240-261 and 263* is/are pending in the application.

4a) Of the above claim(s) *240-249* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *250-261 and 263* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 240-249, drawn to "assessing a viability of human heart tissue by using the computer system to assess a contrast " classified in class 600, subclass 508.

II. Claims 250-261, 263, drawn to " assessing a viability of human heart tissue by assigning a value", classified in class 382, subclass 128.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as subcombinations disclosed as usable together in a single combination. Applicant clearly discloses the two inventions in different embodiment (paragraph [0022]). The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as determine a viability of that section or an adjoining section from the color value. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a

continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. During a telephone conversation with Mr. Eric Meyertons on 03/01/2007 a provisional election was made with traverse to prosecute the invention of facilitating cardiac invention, claims 250-261,263. Affirmation of this election must be made by applicant in replying to this Office action. Claims 240-249 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 251 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "wherein assessing viability of human heart tissue comprises determining viability of human heart tissue" is unclear, because it is unclear what feature or element is being further defined by this claim language, so that the claim fails to clearly point out and distinctly claim applicant's invention.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 250-261, 263 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ishida (US 4,352,988).

As to claim 250, Halmann et al teaches a method of assessing a viability of human heart tissue, comprising: providing one or more images of heart tissue from a human heart to a computer system (generating a plurality of two-dimensional sections of a mammalian heart, column 3, lines 28-29); dividing at least one of the images into a plurality of sections (subjecting the resulting sections to a segmental or helical pattern analysis, column 3, lines 30-35); assigning a value to at least one of the sections, wherein the value is a function of a feature of the section (regional function is color coded, column 2, lines 39-51) ; and using the value of at least one of the sections to assess viability of human heart tissue in or proximate to at least one of the sections with

an assigned value (constructing the three-dimensional , simulation, and animation of a human heart where the model can be used to determine the effect with simulated and real effects on mechanical behavior. The effects of physical and pharmaceutical intervention can also be simulated and real effects on mechanical behavior. The effects of physical and pharmaceutical intervention can also be simulated, for example the colored heart is depicted with colored regions representing stress area, infarcts, wall thickenings, or other myocardial pathologies where the analysis (asses viability) can include suggested diagnosis and intervention and the animation consists of a plurality of 3D images; (column 9, lines 44-46 and figure 1).

As to claim 251, as best understood, Halmann et al teaches the method of claim 250, wherein assessing viability of human heart tissue comprises determining viability of human heart tissue (column 4, lines 62-68).

As to claims 252-253, Halmann et al teaches the method of claim 250, wherein the feature of the section is a color of the section and comprises grayscale. Halmann et al. describe that an artery structure is superimposed on the three-dimensional model of the heart and is represented on a video display. The colored heart is depicted with colored regions representing stress areas, infarcts, wall thickenings, or other myocardial pathologies (column 9, lines 44-66 and Figure 1). Since only certain regions are described as being colored, the regions that are not colored will remain grayscale.

As to claim 254, Halmann teaches the method of claim 250, wherein the computer system divides at least one of the images into a plurality of images (the

obtained two-dimensional images are subject to an edge detection algorithm to serve as a basis for segmented analysis of the sections, column 5, lines 1-5).

As to claim 255, Halmann teaches the method of claim 250, wherein the computer system assigns the value to at least one of the sections (coronary anatomy and its regional function color coded thereon on a computer screen, column 1, lines 5-14).

As to claim 256, Halmann teaches the method of claim 250, further comprising extrapolating at least one feature from at least one of the images (the extracted edges are analogous to features, column 9, lines 16-24).

As to claim 257, Halmann teaches the method of claim 250, wherein the computer system uses the value assigned to at least one of the sections to assess viability of human heart tissue in or proximate to at least one of the sections with an assigned value (the input 34 can serve to provide color animation in real time and can provide color regions 30,31,32, figure 1).

As to claim 258, Halmann teaches the method of claim 250, further comprising creating at least a second image of human heart tissue, wherein at least a portion of the second image appears at least three-dimensional (three dimension reconstruction, column 1, lines 36-41).

As to claim 259-260, Halmann teaches the method of claim 259, further comprising creating at least a second image of human tissue, wherein at least a portion of the second image appears at least with different viabilities and displaying the three-

dimensional image (an artery structure is superimposed on the three dimensional model of the heart and is represented on a video display, figure 1, column 9, lines 44-46).

As to claim 261, Halmann teaches the method of claim 250, further comprising creating a report comprising an image of human heart tissue appearing at least three-dimensional, wherein the image is divided into sections based on the assessed viability of the sections (The model can be used to determine the effects of regional pathology or mechanical dysfunction and can compare these effects with simulated and real effects on mechanical behavior. The effects of physical and pharmaceutical intervention can also be simulated, for example to increase or decrease contractile force. The effects of more rapid or slower heartbeats can be introduced to determine the apparent and real effect on the beating heart. The analysis (access a state of the heart) can include suggested diagnosis and intervention (column 9, lines 44-66 and Figure 1). The animated three-dimensional model is capable of showing the beating of the heart (column 9, lines 44-46) and the animation consists of plurality of three-dimensional images).

Claim 263 differ from claim 251 only in that claim 251 is a method claim whereas; claim 263 is a system claim. Thus, claim 263 is analyzed as previously discussed with respect to claim 251 above.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bardy et al (US 6,398,728) is cited to teach analysis patient care system and method for diagnosing and monitoring respiratory insufficiency and outcomes thereof throughout disease onset, progression, regression, and status quo.

Glossop et al (US 2002/0016541) is cited to teach system which facilitates use of pre-acquired images of an anatomical body to pre-plan and perform medical procedures

Scampini et al (US 2004/0193042) is cited to teach the use of three-dimensional ultrasonic diagnostic imaging to guide the placement and operation of invasive (interventional) medical devices in the body.

Inquiries

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Bitar whose telephone number is 571-270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mancuso can be reached on 571-272-7695. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nancy Bitar 03/01/2007

JOSEPH MANCUSO
SUPERVISORY PATENT EXAMINER

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/22/05,01/28,05,11/02/04,07/30/04,07/27/04.